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PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			EXAMINER BALASUBRAMANIAN, VENKATARAMAN	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/734,039

Applicant(s)

KATH ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24 and 31-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24 and 31-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' response, which included amendment to claim 33, filed on 3/21/2007, is made of record. Claims 24, and 31-54 are pending. In view of applicants' response, the 112 second and first paragraph rejection as pertaining to prodrug is obviated. In addition, 112 first paragraph rejection of claims 41-45 made in the previous office action has been obviated in view of current amendment to claim 43 and cancellation of claims 41, 42, and 44-46. However, the following rejections made in the previous office action are maintained. In addition 112 first paragraph new matter rejection is also applied.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 31-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making pharmaceutically acceptable salts does not reasonably provide enablement for making solvate or hydrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The following apply.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence

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or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

**1. The nature of the invention and the state of the prior art:**

The invention is drawn to compound of formula I, or a pharmaceutically acceptable salt solvate or hydrate thereof. Specification is not adequately enabled as to how to make hydrate of compounds of formula (I) Specification has no example of hydrate of the instant compounds. Specification on page 32, lines 23-25 recites solvate or hydrate thereof but there is no enabling of such compounds.

The compound of formula I embrace 2,4-substitutedamino-5-trifluoromethyl-pyrimidine compounds substituted with variable groups D, E, G, W, X, Y, Z, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> R<sup>4</sup> and R<sup>5</sup>.

Even a cursory calculation of the number of compounds embraced in the instant formula (I) based on the generic definition of alkyl., aryl heteroaryl, heterocyclyl, substituted aryl, heteroaryl, arylalkyloxy, arylalkylthio etc would result in millions and millions of compounds. This is of course not the accurate number and the true number of compounds would far exceed this number of compounds. Thus the genus embraced in the claim 1 is too large and there is no teaching of any solvate or hydrate of this large genus.

Search in the pertinent art, including water as solvent resulted in a pertinent reference, which is indicative of unpredictability of hydrate formation in general. The state of the art is that is not predictable whether solvates or hydrates will form or what their composition will be. In the language of the physical chemist, a hydrate of organic

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molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is the compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. Compared with polymorphs, there is an additional degree of freedom to hydrates, which means a different solvent or even the moisture of the air that might change the stable region of the hydrate. In the instant case of hydrate a similar reasoning therefore apply. Water is a solvent and hence it is held that a pertinent detail of West, which relates to solvates, is also applicable to hydrate

In addition, an additional search resulted in Vippagunta et al., Advanced Drug Delivery Reviews 48: 3-26, 2001, which clearly states that formation of hydrates is unpredictable. See entire document especially page 18, right column section 3.4. Note Vippagunta et al., states "Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for series of related compounds".

**2. The predictability or lack thereof in the art:**

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Hence, the solvate and hydrate as applied to the above-mentioned compounds claimed by the applicant are not art-recognized compounds and hence there should be adequate enabling disclosure in the specification with working example(s).

**3. The amount of direction or guidance present:**

Examples illustrated in the experimental section are limited to making the compounds not related to solvates and hydrates. There is no example of a solvate or hydrate of instant compound. Over 260 compounds were shown in the examples of the specification each of which has come in contact with water and other solvent but there is no showing that instant compounds formed solvates or hydrates. Hence it is clear that merely bring the compound with solvent or water does not result in solvate or hydrate and additional direction or guidance is needed to make them. Specification has no such direction or guidance.

**4. The presence or absence of working examples:**

There is no working example of any solvate or hydrate formed. The claims are drawn to hydrate, yet the numerous examples presented all failed to produce a solvate or hydrate or even hydrate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there, is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ...' no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that hydrates of these

compounds actually exists; if they did, they would have formed. Hence, there should be showing supporting that solvates and hydrates of these compounds exist and therefore can be made.

**5. The breadth of the claims & the quantity of experimentation needed:**

Specication has no support, as noted above, for compounds generically embraced in the claims 24 and 33 would lead to desired solvate and hydrate of the compound of formula I. As noted above, the genus embraces over million compounds and hence the breadth of the claim is broad. The quantity of experimentation needed would be an undue burden on skilled art in the chemical art since there is inadequate guidance given to the skilled artisan for the many reasons stated above. Even with the undue burden of experimentation, there is no guarantee that one would get the product of desired hydrate of compound of formula I embraced in the instant claims in view of the pertinent reference teachings.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to make Applicants' invention.

This rejection is same as made in the previous office action. Applicants' argument to overcome this rejection is not persuasive for reasons of record.

Contrary to applicants' urging, examiner had made a proper rejection based on proper analysis of Wands factor and with supporting document. Applicants have not provided any direct evidence that the millions and millions have compounds embraced in the instant genus form solvate or hydrate. In fact a careful counting of the genus of compounds would probably exceed trillion compounds given the generic nature of the various variable groups and the number of variable groups embraced. Again examples in the specification which have come in contact with solvent and or water have not formed solvate or hydrate.

Contrary to applicants' assessment of solvate or hydrate as dispersion in solvent or water( based on Stedman), a solvate or hydrate in fact compounds formed with solvent or water of crystallization and this clearly taught in the two references cited by the examiner. Furthermore, there is no way of predicting which compound would form solvate or hydrate. Specification also does not teach or suggest which compound would form solvate with which solvent . Since none of the exemplified compounds have formed solvate or hydrate, there is no guidance in the instant specification for making solvate or hydrate of the instant compounds. As noted before, prior art are indicative of unpredictability of solvate or hydrate formation of a given compound. Thus given the huge genus and the number solvents, one trained in the art had to unduly extensive experimentation to see whether instant compounds form solvate or hydrate if at all they form.

Also, note MPEP 2164.08(b) which states that claims that read on "... significant numbers of inoperative embodiments would render claims nonenabled when the



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specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.". Clearly that is the case here.

Hence, this rejection is proper and is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahmann et al., US2003/0171359 for reasons of record. To repeat:

Dahmann et al. teaches several 2,4 substitutedaminopyrimidine compounds for treating abnormal cell growth, which includes instant compounds. See pages 1-5, formula 1 and note the definition of various variable groups  $R^a$ ,  $R^b$ ,  $R^c$ ,  $R^d$  and  $R^e$ . Especially note with the given definition of  $R^a$ ,  $R^b$ ,  $R^c$ ,  $R^d$  and  $R^e$ , compounds taught by Dahmann et al. include instant compounds. See entire document for further details. See pages 23-86 for large number of examples of compounds made. Note claims 25-30 are rejected as method of use of Dahmann et al. include breast cancer.

Dahmann et al. differs from the instant claims in exemplifying only limited number of compounds of the genus claimed in page 1 for compound of formula I. However, Dahmann et al. teaches equivalency of those compounds taught in pages 23-86 with those generically recited in pages 1-5.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Dahmann et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action now limited claims 31-54. Applicants' traversal to overcome this rejection is not persuasive.

As acknowledged by applicants, Dahmann et al., teaches  $R^c$ -N- $R^d$  group at 4-position of the pyrimidine ring, which include aralkyl for  $R^c$  and  $R^d$ , and an alkyl substituted with aryl or heteroaryl. Note the substituents on aryl or heteroaryl or all choices of  $R^c$  or  $R^d$  include instant substituents for  $R^4$ . Compounds taught include  $NHSO_2R$ . See examples Hence, when instant A is NH, B is absent or B is  $NR^6$  and A is absent, the compounds embraced in the instant claims include compounds taught by Dahmann et al. Dahmann et al., teaches equivalency of the exemplified compounds with those generically claimed. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Dahmann et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

No hindsight analysis is required. One trained in the art can make whatever compounds embraced in the genus using the teaching of the exemplified compounds and expect the resultant compounds to have the use taught therein. This clearly true for instant genus which is also very large. As recited, it implies that all the compounds of the instant genus would have the said utility and hence one trained in the art would make compounds of the instant genus based on the exemplified compounds (about 265 compounds out of millions and millions of compounds of the instant genus).

There is guidance in the reference to make such substituted compounds. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds including those bearing a  $R^4$  or  $R^5$  group as optionally substituted  $Y_{(n)}$ -mono-ring group or optionally substituted  $Y_{(n)}$  -multi-ring

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group bearing  $SR^8$ ,  $SO_2R^8$ ,  $NR^8SO_2R^9$  etc., using the teachings of Nagarathnam et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

As for applicants' assessment that the genus of Dahmann et al., is broad and one need to choose from large number substituents, as pointed above there is adequate guidance in Dahmann. In addition, instant genus includes million and millions of compounds and one were estimate accurately it would probably exceed trillion compounds. Based on applicants' argument, it is deduced that one will be able to make all these millions of compounds or trillions of compounds and expect to have the desired use based on the teachings of the species in claim 24. The same reason is also applicable to the genus of Dahmann et al.

Hence, this rejection is proper and is maintained.

Claims 31-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagarathnam et al., WO 03/030909 for reasons of record.

Nagarathnam et al. teaches several 2,4-substitutedaminopyrimidine compounds for treating viral infection and cancer, which include instant compounds. See pages 3-10, formula 1 and note the definition of various variable groups X,  $R^2$  and  $R^3$ . Especially note with the given definition of X,  $R^2$  and  $R^3$ , compounds taught by Nagarathnam et al. include instant compounds. See entire document for further details. See pages 27-87 including Table 1-3 for large number of examples of compounds made. Note claims 25-30 are rejected as method of use of Nagarathnam et al. include breast cancer.

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Nagarathnam et al. differs from the instant claims in not exemplifying only all the compounds of the genus claimed in pages 3-10 for compound of formula I. However, Nagarathnam et al. teaches equivalency of those compounds taught in pages 27-87 with those generically recited in pages 3-10.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Nagarathnam et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action. Applicants' traversal is not persuasive.

Contrary to applicants' urging, Nagarathnam et al., teaches NH fused aryl or heteroaryl at 2-position of pyrimidine ring and the Y definition meets the  $-(CR^2R^3)_n$  requirement. See definition of Y. Note  $R^4$  can be optionally substituted  $Y_{(n)}$ -mono-ring group or optionally substituted  $Y_{(n)}$ -multi-ring group. See page 4, lines 1-29. Note the substituents on these ring include instant  $R^4$  groups. See Table 4 and note  $R^5$  groups which include  $SO_2NH_2$ . There is guidance in the reference to make such substituted compounds. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds including those bearing a  $R^4$  or  $R^5$  group as optionally substituted  $Y_{(n)}$ -mono-ring group or optionally substituted  $Y_{(n)}$ -multi-ring group bearing  $SR^8$ ,  $SO_2R^8$ ,  $NR^8SO_2R^9$  etc., using the teachings of Nagarathnam et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

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As for applicants' assessment that the genus of Nagarathnam et al., is broad and one need to choose from a large number of substituents, as pointed out above there is adequate guidance in Nagarathnam. In addition, instant genus includes million and millions of compounds and one were estimate accurately it would probably exceed trillion compounds. Based on applicants argument, it is deduced that one will be able to make all these millions of compounds or trillions of compounds and expect to have the desired use based on the teachings of the species in claim 24. The same reason is also applicable to the genus of Nagarathnam et al.

Hence this rejection is proper and is maintained.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24 and 31-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25 of copending Application No. 11/127,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter

embraced in the instant claims is also embraced in the copending application 11/127,676. Note substituents in 2, 4 and 5 position of the instant claims overlap with those of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 24 and 31-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/124,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims is also embraced in the copending application 11/124,006. Note substituents in 2, 4 and 5 position of the instant claims overlap with those of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

All the above double patenting rejections are same as made in the previous office action except that they are now applied to currently pending claims. As noted above in each case, the subject matter embraced in the instant claims are also embraced in the copending applications. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of copending application and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above. Hence, these rejections are proper.

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Applicants' have differed addressing these rejections. These rejections are proper and are maintained.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Acting Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

  
Venkataraman Balasubramanian

5/23/2007